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10/551,789	07/05/2006	Michael Thomas Clandinin	D4858-00059	3396

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EXAMINER	
OLSON, ERIC	
ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,789	CLANDININ, MICHAEL THOMAS	
	Examiner	Art Unit	
	ERIC S. OLSON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-7,11,13,17,19-23,25 and 28-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-7,11,13,17,19-23,25 and 28-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/6/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This office action is a response to applicant's communication submitted February 5, 2008 wherein claims 13 and 25 are amended, claims 8-10 and 12 are cancelled, and new claims 28-32 are introduced. This application is a national stage application of PCT/CA04/00375, filed March 12, 2004, which claims benefit of US application 10/404095, now US patent 6998392, filed April 2, 2003.

Claims 2-7, 11, 13, 17, 19-23, 25, and 28-32 are pending in this application.

Claims 2-7, 11, 13, 17, 19-23, 25, and 28-32 as amended are examined on the merits herein.

Applicant's amendment, submitted February 5, 2009, with respect to the rejection of instant claims 9 and 10 under 35 USC 112, first paragraph, for lacking enablement for methods of preventing disease, has been fully considered and found to be persuasive to remove the rejection as the rejected claims have been cancelled. Therefore the rejection is withdrawn.

Applicant's amendment necessitates the following new grounds of rejection:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25, 28, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Della Valle et al. (US patent 5190925, cited in PTO-1449 3/20/2006) in view of the Merck Manual of Diagnosis and Therapy (Cited in PTO-892, herein referred to as Merck) in view of Schroten. (PCT international publication WO96/058444, of record in previous action).

Della Valle et al. discloses a method for treating neural destruction and autonomic dysfunction in Chagas' disease by administering a mixture of gangliosides. (column 2 lines 40-52) Chagas' disease is disclosed to produce myocardial inflammation. (column 1 lines 35-40, 63-66) Thus Chagas' disease is an inflammatory disease and subjects suffering from Chagas' disease are reasonably considered to be suffering from inflammation. Typical pharmaceutical compositions according to this invention include the gangliosides GM1, GD1a, GD1b, GT1b, GD3, and GQ1b. (column 7 line 60 - column 8 line 10) Because subjects of the invention are suffering from inflammation, administering this composition is reasonably considered to be a method of mediating inflammation. The dose of gangliosides administered is preferably about 10-100 mg per day of gangliosides. (column 8 lines 35-45) Della Valle et al. does not disclose oral administration of the gangliosides, for example as a supplemented food. Della Valle et al. also does not disclose administration of gangliosides to an infant.

Merck discloses that Chagas' disease can be transmitted transplacentally, that is to infants during gestation. (p. 1249, left column last paragraph - right column first paragraph) Transmission occurs in about 1-5% of pregnancies involving chronically

infected women and chronic neonatal disease has a high mortality. (p. 1250 left column third paragraph)

Schroten discloses gangliosides that are useful for treating allergies, particularly in infants and small children. (abstract, p. 2 lines 6-9) The gangliosides are added to a food formula resulting in a supplemented food. (p. 2 lines 23-34) Therefore ganglioside therapeutic agents are seen to be suitable for oral administration.

It would have been obvious to one of ordinary skill in the art to administer the ganglioside composition described by Della Valle et al. to infants suffering from Chagas' disease, and to administer the composition orally. One of ordinary skill in the art would have been motivated to administer the composition to infants because Merck discloses that infants can be infected with Chagas' disease. One of ordinary skill in the art would have reasonably expected success because Della Valle discloses treating Chagas' disease in human patients generally. One of ordinary skill in the art would have been motivated to administer the composition orally because Schroten discloses that gangliosides can be administered orally in a supplemented food such as an infant food. One of ordinary skill in the art would have reasonably expected success because oral administration of therapeutic agents is well known and routine in the art.

Therefore the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment necessitated this rejection, the rejection is made **FINAL**.

Claims 2-7, 11, 13, 17, 19-23, 25, and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ettinger (US patent 4762822, cited in PTO-1449 3/20/2006)

in view of Pan et al. (Reference included with PTO-892 7/21/2008) in view of the Merck Manual of Diagnosis and Therapy. (Reference included with PTO-892, herein referred to as Merck)

Ettinger discloses an improved food for young mammals comprising a sialic acid or a ganglioside, for example gangliosides extracted from mammalian brain, human milk, or human colostrum. (column 3 lines 5-17) This composition reduces the number of gastrointestinal disease producing microorganisms in the mammal's gastrointestinal tract. (column 1 lines 19-32) Administering the ganglioside to as subject is reasonably considered to be a method of mediating inflammation in the subject. A young mammal according to the invention refers to mammals such as humans that have not been weaned, i.e. infants. (column 4 lines 64-68) The amount of sialic acid or ganglioside is sufficient to provide about 0.0003-0.02%, preferably 0.005-0.015% of the subject's body weight. (column 6 lines 56-63) This amount would be equivalent to 9.6-640 mg for a 3.2 kg infant or 210-14000 mg for a 70 kg adult. Compositions of gangliosides were disclosed to have a lethal effect on *E.* coli in culture. (column 9 line 52 - column 10 line 28) Ettinger does not specifically disclose the various gangliosides used in the instant claims, for example GDE, GM2, GM3, and GD1b. Ettinger also does not disclose the exact amount of ganglioside (10-50 mg) administered to an infant subject or the amount of 100-1000 mg administered to an adult subject.

Pan et al. discloses a study of the ganglioside composition of human colostrum and milk, ad well as cow's milk. (p. 26 paragraphs 1-3) Human colostrum contains over

50% of ganglioside GD3, as well as a smaller amount of ganglioside GM3. (p. 29 table 1)

Merck discloses that a typical newborn infant weighs about 3.2 kg. (p. 2084 left column fifth paragraph) Merck also discloses that certain strains of *e. coli* produce shigella toxin and can cause gastrointestinal disease. (p. 285 right column paragraphs 2-3)

It would have been obvious to one of ordinary skill in the art to administer 100-1000 mg of ganglioside to an adult or 10-50 mg to an infant suffering from *E. coli* gastrointestinal infection. One of ordinary skill in the art would have been motivated to use these amounts because they fall within the broad ranges disclosed by Ettinger. When the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). See MPEP § 2144.05 [R-1].

Furthermore it would have been obvious to administer the compositions of Ettinger to an adult mammal suffering from *E. coli* infection. One of ordinary skill in the art would have been motivated to do so because adults as well as infants can contract this infection. One of ordinary skill in the art would reasonably have expected success because Ettinger already discloses that gangliosides are toxic to *E. coli*.

Finally it would have been obvious to use a composition comprising the specific amounts of gangliosides GM3 and GD3 recited in the instant claims. One of ordinary skill in the art would have been motivated to include GM3 and GD3 in the composition

because both of these gangliosides are present in significant amount in human colostrum and milk as described by Pan et al. One of ordinary skill in the art would have been able to modify and select the optimal ranges for these components in order to practice the invention. Doing so is part of the ordinary and routine level of skill in the art and would therefore be reasonably expected to succeed.

Therefore the invention taken as a whole is *prima facie* obvious. Because Applicant's amendment necessitated this new ground of rejection, the rejection is made **FINAL**.

The following rejections of record in the previous action are maintained:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 17, 23, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Williams et al. (US pre-grant publication 2004/0047856, of record in previous action)

Williams et al. discloses a composition comprising colostrum, hyperimmune milk, and a ganglioside. (p. 2 paragraphs 0020-0021) Preferably the gangliosides include GM_3 and GD_3. (p. 2 paragraph 0033) This composition can be used in a method of

treating an infection, for example *H. pylori* or *C. difficile*, or alternately irritable bowel syndrome or an arthritic condition. (p. 3 paragraphs 0042-0045) This composition is inherently considered to be a supplemented liquid or food as it comprises milk, a liquid food, supplemented with additional ganglioside. Furthermore, it is considered to be an infant food as it is suitable for administration to infants. Finally, a process of administering this food to a patient is seen to inherently accomplish the effect of lowering the patient's plasma cholesterol, anticipating the method of claim 25. The steps disclosed in the reference are the same as in the instant claims, administering the same compound in the same amounts to the same or similar cells or subjects by the same mode of administration. See *Ex parte Novitski* 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Note that the claiming of a new use, new function, or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3c. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it relates to the claimed invention herein. Therefore Williams et al. anticipates the claimed invention.

Response to Argument: Applicant's arguments, submitted February 5, 2009, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the claims have been amended to require a dosage level that is not taught by Williams et al. However, claims 17, 23, and 25 do not require any particular dosage level. Also, although Applicant has amended the claims to require that the treatment method have certain effects on

plasma cholesterol, lipid components, platelet activating factor, and total diglyceride, these effects are seen to be inherent effects of administering gangliosides to a subject. Therefore they do not serve to differentiate the claims from the prior art.

For these reasons the rejection is deemed proper and made **FINAL**.

Claims 17, 19, 23, and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Berger et al. (US pre-grant publication 2005/0107311, of record in previous action)

Berger et al. discloses gangliosides obtained from buffalo milk which mediate anti-inflammatory effects. (p. 1 paragraphs 0018-0019) Gangliosides present include GM3 and GD3. (p. 3 paragraph 0066) One specific type of buffalo milk (Pakistan buffalo mature milk) is analyzed and shown to have predominantly (over 50%) ganglioside GD3. (figure 1 in the drawings, also p. 2 paragraph 0031) This composition is a nutritionally complete consumable product, and therefore is a supplemented food. (p. 2 paragraph 0050) It can also be used in infant formulas. (p. 2 paragraph 0028) Finally, a process of administering this food to a patient is seen to inherently accomplish the effect of lowering the patient's plasma cholesterol, anticipating the method of claim 25. The steps disclosed in the reference are the same as in the instant claims, administering the same compound in the same amounts to the same or similar cells or subjects by the same mode of administration. See *Ex parte Novitski* 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Note that the claiming of a new use, new function, or unknown property which is inherently present in the prior art does not make the claim patentable.

See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3c. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it relates to the claimed invention herein. Therefore Berger et al. anticipates the claimed invention.

Response to Argument: Applicant's arguments, submitted February 5, 2009, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the claims have been amended to require a dosage level that is not taught by Berger et al. However, claims 17, 19, 23, and 25 do not require any particular dosage level. Also, although Applicant has amended the claims to require that the treatment method have certain effects on plasma cholesterol, lipid components, platelet activating factor, and total diglyceride, these effects are seen to be inherent effects of administering gangliosides to a subject. Therefore they do not serve to differentiate the claims from the prior art.

For these reasons the rejection is deemed proper and made **FINAL**.

Claims 17, 23, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Schroten. (PCT international publication WO96/058444, of record in previous action)

Schroten discloses gangliosides that are useful for treating allergies, particularly in infants and small children. (abstract, p. 2 lines 6-9) The gangliosides are added to a food formula resulting in a supplemented food. (p. 2 lines 23-34) A preferred embodiment contains 1 mg of GM3, 30 mg of GD3, and 15 mg of GTb1. (p. 4 lines 26-28) This composition therefore comprises over 50% of GD3. Finally, a process of

administering this food to a patient is seen to inherently accomplish the effect of lowering the patient's plasma cholesterol, anticipating the method of claim 25. The steps disclosed in the reference are the same as in the instant claims, administering the same compound in the same amounts to the same or similar cells or subjects by the same mode of administration. See *Ex parte Novitski* 26 USPQ 2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Note that the claiming of a new use, new function, or unknown property which is inherently present in the prior art does not make the claim patentable. See *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also *Eli Lilly and Co. v. Barr Laboratories Inc.* 251 F3c. 955; 58 USPQ2d 1869-1881 (Fed. Cir. 2001) with regard to inherency as it relates to the claimed invention herein. Therefore Schroten anticipates the claimed invention.

Response to Argument: Applicant's arguments, submitted February 5, 2009, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the claims have been amended to require a dosage level that is not taught by Schroten et al. However, claims 17, 23, and 25 do not require any particular dosage level. Also, although Applicant has amended the claims to require that the treatment method have certain effects on plasma cholesterol, lipid components, platelet activating factor, and total diglyceride, these effects are seen to be inherent effects of administering gangliosides to a subject. Therefore they do not serve to differentiate the claims from the prior art.

For these reasons the rejection is deemed proper and made **FINAL**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (US pre-grant publication 2004/0047856, of record in previous action)

The disclosure of Williams et al. is discussed above. Williams et al. does not disclose a method wherein the composition comprises the specific amounts of GD3 and GM3 recited in instant claims 4-7 and 19-22.

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the methods of Williams et al. using the specific amounts of GM3 and GD3 found in claims 4-7 and 19-22. One of ordinary skill in the art would have been motivated to optimize the amounts of these critical ingredients in the therapeutic composition in order to determine the optimal amounts to use to get the desired therapeutic effect. One of ordinary skill in the art would have reasonably expected success because routine optimization of the amounts of ingredients in a prior art composition is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted February 5, 2009, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments are the same as those

made with respect to the rejection of claims 17, 23, and 25 under 35 USC 102 over Williams et al. above, and are not found to be persuasive for the same reasons. Therefore the rejection is deemed proper and made **FINAL**.

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berger et al. (US pre-grant publication 2005/0107311, of record in previous action)

The disclosure of Berger et al. is discussed above. Berger et al. does not disclose a method wherein the composition comprises the specific amounts of GD3 and GM3 recited in instant claims 4-7 and 19-22.

It would have been obvious to one of ordinary skill in the art at the time of the invention to practice the methods of Berger et al. using the specific amounts of GM3 and GD3 found in claims 4-7 and 19-22. One of ordinary skill in the art would have been motivated to optimize the amounts of these critical ingredients in the therapeutic composition in order to determine the optimal amounts to use to get the desired therapeutic effect. One of ordinary skill in the art would have reasonably expected success because routine optimization of the amounts of ingredients in a prior art composition is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Response to Argument: Applicant's arguments, submitted February 5, 2009, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant's arguments are the same as those made with respect to the rejection of claims 17, 23, and 25 under 35 USC 102 over

Berger et al. above, and are not found to be persuasive for the same reasons.

Therefore the rejection is deemed proper and made **FINAL**.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17, 19, 21-23, and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6998392. (Cited in previous action, herein referred to as '392) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-5 of '392 anticipate the claimed invention. Specifically, claim 1 of '392 is drawn to a method comprising administering a ganglioside to a subject. Administering a ganglioside inherently will mediate inflammation and lower serum

cholesterol. Claim 2 indicates that the ganglioside contains GD3 and/or GM3, and clam 5 recites a composition falling within the amounts of GD3 and GM3 recited in instant claims 19, 21, and 22. Claims 3 and 4 require that the composition be a supplemented liquid or food, including an infant formula, anticipating instant claims 11, 12, 23, and 24. Therefore '392 anticipates the claimed invention.

Response to Argument: Applicant's arguments, submitted February 5, 2009, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the claims have been amended to require dosages and requirements to change lipid components in microdomains. However, claims 17, 19, and 21-23 as amended still do not recite any required dosage, and the effects of these gangliosides on lipid microdomains is an inherent effect of the composition being administered and thus does not serve to differentiate the claims as amended from those of '392. Therefore the rejection is maintained and made **FINAL**.

Claims 17, 23, and 25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-17 of copending Application No. 11/622858. (Published as 2007/0173480, cited in previous action) Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 9-17 of '858 anticipate the claimed invention. Specifically, claim 9 of '858 is drawn to a method of treating an inflammatory bowel disorder by administering a ganglioside and claim 16 is drawn to a similar method of

lowering blood cholesterol. Claims 13 and 17 of '858 indicate that the ganglioside can include GD3 and/or GM3. Claims 14 and 15 of '858 specify that the composition is a supplemented liquid or food, or an infant formula. Therefore '858 anticipates the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Argument: Applicant's arguments, submitted February 5, 2009, with respect to the above ground of rejection, have been fully considered and not found to be persuasive to remove the rejection. Applicant argues that the claims have been amended to require dosages and requirements to change lipid components in microdomains. However, claims 17, 23, and 25 as amended still do not recite any required dosage, and the effects of these gangliosides on lipid microdomains is an inherent effect of the composition being administered and thus does not serve to differentiate the claims as amended from those of '858. Therefore the rejection is maintained and made **FINAL**.

Conclusion

No claims are allowed in this application. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
5/12/2009

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623